

US009844544B2

## (12) United States Patent

Tu et al.

(10) Patent No.: US 9,844,544 B2

(45) **Date of Patent:** \*Dec. 19, 2017

# (54) METHYLPHENIDATE EXTENDED RELEASE CHEWABLE TABLET

## (71) Applicant: TRIS Pharma, Inc., Monmouth

Junction, NJ (US)

(72) Inventors: Yu-Hsing Tu, West Windsor, NJ (US);

**Ashok Perumal**, Monmouth Junction, NJ (US); **Kalyan Kathala**, Monmouth

Junction, NJ (US)

(73) Assignee: TRIS PHARMA, INC, Monmouth

Junction, NJ (US)

(\*) Notice: Subject to any disclaimer, the term of this

patent is extended or adjusted under 35

U.S.C. 154(b) by 0 days.

This patent is subject to a terminal dis-

claimer.

(21) Appl. No.: 15/009,480

(22) Filed: Jan. 28, 2016

## (65) Prior Publication Data

US 2016/0143846 A1 May 26, 2016

## Related U.S. Application Data

- (63) Continuation of application No. 14/872,226, filed on Oct. 1, 2015, now Pat. No. 9,295,642, which is a continuation of application No. 14/624,998, filed on Feb. 18, 2015, now Pat. No. 9,180,100, which is a continuation of application No. 14/300,580, filed on Jun. 10, 2014, now Pat. No. 8,999,386, which is a continuation of application No. PCT/US2013/054930, filed on Aug. 14, 2013.
- (60) Provisional application No. 61/774,783, filed on Mar. 8, 2013, provisional application No. 61/683,513, filed on Aug. 15, 2012.

(51)	Int. Cl.	
	A61K 31/4458	(2006.01)
	A61K 9/00	(2006.01)
	A61K 9/20	(2006.01)
	A61K 9/28	(2006.01)
	A61K 9/50	(2006.01)

(52) **U.S. Cl.** CPC .......

CPC ....... A61K 31/4458 (2013.01); A61K 9/0056 (2013.01); A61K 9/20 (2013.01); A61K 9/2027 (2013.01); A61K 9/2054 (2013.01); A61K 9/2072 (2013.01); A61K 9/2077 (2013.01); A61K 9/2081 (2013.01); A61K 9/2086 (2013.01); A61K 9/2846 (2013.01); A61K 9/5026 (2013.01)

(58) Field of Classification Search

#### (56) References Cited

#### U.S. PATENT DOCUMENTS

2,990,332 A	6/1961	Keating et al.
3,138,525 A	6/1964	Koff
3,499,960 A	3/1970	Macek
3,594,470 A	7/1971	Borodkin
3,979,349 A	9/1976	Fink
4,221,778 A	9/1980	Raghunathan
4,510,128 A	4/1985	Khanna
4,600,645 A	7/1986	Ghebre-Sellasie
4,762,709 A	8/1988	Sheumaker
4,765,989 A	8/1988	Wong
4,794,001 A	12/1988	Mehta
4,871,549 A	10/1989	Veda
4,876,094 A	10/1989	Benton
4,891,230 A	1/1990	Geoghegan
4,894,239 A	1/1990	Nonomura et al.
4,910,214 A	3/1990	Karjalainen
4,952,402 A	8/1990	Sparks
4,961,932 A	10/1990	Theeuwes
4,996,047 A	2/1991	Kelleher et al.
4,999,189 A	3/1991	Kogan
5,032,393 A	7/1991	Douglas
5,093,200 A	3/1992	Watanabe
5,156,850 A	10/1992	Wong et al.
5,186,930 A	2/1993	Kogan
5,219,563 A	6/1993	Douglas
(Continued)		

## FOREIGN PATENT DOCUMENTS

BE	729827	9/1969
CA	2742680	5/2010
	(Continued)	

#### OTHER PUBLICATIONS

Ahmann, Placebo-Controlled Evaluation of Amphetamine Mixture-Dextroamphetamine Salts and amphetamine Salts (Adderall): Efficacy Rate and Side Effects, Pediatrics, 107(1): 1, Jan. 1, 2001. BASF Product Catalog, BASF Fine Chemicals, Switzerland, Aug. 2008.

Chourasia, "Pharmaceutical Approaches to Colon Targeted Drug Delivery Systems", J. Pharm. Pharmaceutic. Sci. 6(1):33-66, Jan.-Apr. 2003.

(Continued)

Primary Examiner — Micah Paul Young (74) Attorney, Agent, or Firm — Howson & Howson LLP; Cathy A. Kodroff; Egon Berg

## (57) ABSTRACT

An oral methylphenidate extended release tablet is described, which can be scored and still retain its extended release profile. The tablet contains a combination of an uncoated methylphenidate-ion exchange resin complex, a barrier coated methylphenidate-ion exchange resin complex-matrix, and an uncomplexed methylphenidate active component. Following administration of a single dose of the extended release methylphenidate chewable tablet, a therapeutically effective amount of methylphenidate is reached in less than about 20 minutes and the composition provides a twelve-hour extended release profile.

### 40 Claims, 1 Drawing Sheet